RESPONSE

I. Status of the Claims

No claims have been cancelled. No claims have been amended. No new claims have been added.

Claims 1 and 3-16 are therefore presently pending in the case. For the convenience of the Examiner, a clean copy of the pending claims is attached hereto as **Exhibit A**.

II. Rejection of Claims 1 and 3-16 Under 35 U.S.C. § 101

The Action first rejects claims 1 and 3-16 under 35 U.S.C. § 101, as allegedly lacking a patentable utility. Applicants respectfully traverse.

In the response filed on May 15, 2003 ("the previous response") to the First Office Action in this case, which was mailed on February 19, 2003 ("the First Action"), Applicants invited the Examiner's attention to the fact a sequence sharing **100% percent identity at the protein level** over the entire length of SEQ ID NO:2 is present in the leading scientific repository for biological sequence data (GenBank), and has been annotated by third party scientists *wholly unaffiliated with Applicants* as "Homo sapiens mRNA for mitochondrial RNA splicing protein 3/4 (HMRS3/4 gene)" (GenBank accession number AJ303077; alignment and GenBank report provided in **Exhibit B**). Applicants also pointed out that the HMRS3/4 gene has been shown by these scientists to restore mitochondrial function in yeast lacking the mrs3 and mrs4 genes (Li *et al.*, 2001, *FEBS Lett.* 494:79-84; abstract provided in **Exhibit C**). In fact, the involvement of the yeast MRS3 and MRS4 proteins in RNA splicing has been known for over a decade (Wiesenberger *et al.*, *J. Mol. Biol.* 217:23-37, 1991; abstract provided in **Exhibit D**). Applicants further invite the Examiner's attention to the fact that two additional sequences sharing 100% percent **identity at the protein level** over the entire length of SEQ ID NO:2 are present in GenBank, and have been annotated by third party scientists *wholly unaffiliated with Applicants* as "Homo sapiens solute carrier family 25, member 28" (GenBank accession numbers BC047312 and BC058937; alignments and GenBank reports provided in **Exhibit E**). Applicants also pointed out in the previous response that the specification as originally filed describes the presently claimed sequences as mitochondrial proteins that have a role in RNA splicing (at least at page 2, lines 10-11, of the specification). Applicants reiterate that the legal test for

utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. Given these GenBank annotations and references, there can be no question that those skilled in the art would clearly believe that Applicants' sequence is a mitochondrial protein involved in RNA splicing.

Thus, the present situation exactly tracks Example 10 of the Revised Interim Utility Guidelines Training Materials (pages 53-55; **Exhibit F**), which clearly establishes that a rejection under 35 U.S.C. § 101 as allegedly lacking a patentable utility and under 35 U.S.C. § 112, first paragraph as allegedly unusable by the skilled artisan due to the alleged lack of patentable utility (see Section III, below), is not proper when a full length sequence (such as the presently claimed sequences) has a similarity score greater than 95% to a protein having a known function (such as the **100% identity** between SEQ ID NO:2 and HMRS3/4, as discussed above). Therefore, the United States Patent and Trademark Office's own examination guidelines clearly indicate that the present claims meet the requirements of 35 U.S.C. § 101, and the rejection of record should be withdrawn.

In the face of this evidence, the Examiner still alleges that the claimed invention does not have a patentable utility, and presents a number of arguments to support this allegation. The Examiner first notes that "Applicants have characterized the polynucleotides as those that encode novel human mitochondrial proteins which (*sic*) share structural motifs typical of mitochondrial solute carriers, RNA splicing proteins, uncoupling proteins and mitochondrial carrier proteins", but "do not first of all provide the information as to which specific polypeptide has which specific function" (Action at page 2). Applicants respectfully point out that Li *et al.* clearly state that the human MRS3/4 RNA splicing protein that they identified and characterized "belong to the family of mitochondrial carrier proteins" (see **Exhibit C**), and the GenBank report for the human MRS3/4 protein also characterizes this protein as a "mitochondrial solute carrier" (see **Exhibit B**), which is the exact same designation given to this same exact protein by other scientists (see **Exhibit E**). Furthermore, the relationship between mitochondrial carrier proteins, RNA splicing proteins and uncoupling proteins has been known in the art for over a decade (see **Exhibit D**). Thus, as skilled artisans clearly understands the functional relationship between "mitochondrial solute carriers, RNA splicing proteins, uncoupling proteins and mitochondrial carrier proteins", this argument completely fails to support the Examiner's allegation that the presently claimed sequences lack a patentable utility.

Next, the Examiner questions Applicants' assertion that "there can be no question that those

skilled in the art would clearly believe that applicants' sequence is a mitochondrial protein involved in RNA splicing" because "applicants do not make it clear as to with (*sic*) which SEQ ID NO is the 100% match" (Action at page 4). First, Applicants respectfully point out that as the alignment presented in the previous response is 364 amino acids in length, and **only** SEQ ID NO:2 (364 amino acids in length) out of all of the amino acid sequences disclosed in the present application is as long as 364 amino acids, common sense would dictate that SEQ ID NO:2 "is the 100% match". Nevertheless, in order to avoid any possible confusion, Applicants have stated for the record that the alignments described above are to SEQ ID NO:2. Additionally, Applicants provide herewith the alignments of SEQ ID NO:4 (**Exhibit G**), SEQ ID NO:6 (**Exhibit H**) and SEQ ID NO:12 (**Exhibit I**) with the above referenced GenBank sequences. However, Applicants respectfully point out is has long been established that not all species of an invention need to have the same function in order to be patentable. Additionally, as the Examiner himself has determined that the claimed species are not patentably distinct, the entire discussion of the function of the different species is completely irrelevant. Thus, this argument also fails to support the Examiner's allegation that the presently claimed sequences lack a patentable utility.

The Examiner further alleges that the claimed invention lacks a patentable utility because the specification does not denote "which specific RNA is spliced by" the claimed sequences (Action at page 2). Applicants respectfully point out that even the United States Patent and Trademark Office recognizes that this is obviously **not** the standard for meeting the requirements of 35 U.S.C. § 101, as evidenced most clearly by Example 10 of the Revised Interim Utility Guidelines Training Materials (see **Exhibit F**), which uses the example of a DNA ligase having a similarity score of 95% to known DNA ligases as meeting the utility requirement under 35 U.S.C. § 101. Note that there is absolutely **no requirement whatsoever** in Example 10 that information about which DNA is ligated by the claimed novel DNA ligase is needed in order to meet the requirements of 35 U.S.C. § 101. Thus, this argument completely fails to support the Examiner's allegation that the presently claimed sequences lack a patentable utility.

Applicants also pointed out in the previous response that, as set forth by the Federal Circuit, "(t)he threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip Inc. v. Orange Bang Inc.*, 51 USPQ2d 1700 (Fed. Cir. 1999) (citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966)). Additionally, the Federal

Circuit has stated that "(t)o violate § 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992), emphasis added. *Cross v. Iizuka* (224 USPQ 739 (Fed. Cir. 1985); "*Cross*") states "any utility of the claimed compounds is sufficient to satisfy 35 U.S.C. § 101". *Cross* at 748, emphasis added. Indeed, the Federal Circuit recently emphatically confirmed that "anything under the sun that is made by man" is patentable *(State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 47 USPQ2d 1596, 1600 (Fed. Cir. 1998), citing the U.S. Supreme Court's decision in *Diamond vs. Chakrabarty*, 206 USPQ 193 (S.Ct. 1980)).

The Examiner seems to discount the case law cited by Applicants, stating "that in *Juicy Whip Inc. v. Orange Bang Inc.*, the issue of utility was with regard to a juice dispenser, in *Brooktree Corp. v. Advanced Micro Devices, Inc.*, the issue of utility was regarding a digital to analog conversion circuitry, and in *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, the issue of utility was regarding a business method" and that "it is beyond the scope of this Office action at this time during the prosecution of this case to respond to each one without knowing the claims involved and the prosecution history of each of the cases cited" (Action bridging pages 4 and 5). Applicants respectfully point out that it is **not** the job of the Examiner to consider "the claims involved and the prosecution history of each of the cases cited", but, rather, as the holding in these cases is **mandatory legal authority**, to follow the precedent as applied to the broad issue at hand in each cited case, unless a case is specifically limited to it's facts by the **Court itself**. Furthermore, Section 101 of the Patent Act of 1952, 35 U.S.C. § 101, provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," may obtain a patent on the invention or discovery. Applicants point out that 35 U.S.C. § 101 covers devices (machines) as well as compositions, and makes no distinction between the two with regard to meeting the burden of complying with 35 U.S.C. § 101. Additionally, *Juicy Whip Inc. v. Orange Bang Inc.* cites *Brenner v. Manson*, 383 U.S. 519 (1966), which the Examiner obviously believes is relevant to the present case, since the Examiner himself cites this exact case in the Action (Action at page 6). Also, *Cross* and *Diamond vs. Chakrabarty, supra*, specifically concern compositions. Thus, this argument is completely improper, and totally fails to support the alleged lack of utility of the presently claimed compositions.

The Examiner next states that "Applicants argument that a third party validated (*sic*) the utility

in a post-dated reference overcomes the instant utility (*sic*) is highly misplaced" because "(i)n view of the large amount of information unknown in regard to the claimed invention, it is not reasonable for one of skill in the art to conclude that the additional research required to practice the claimed invention is merely routine" (Action at page 6). Applicants completely disagree, and respectfully point out that, as described in great detail above, in fact a large amount of information is not only known by skilled artisans about the presently claimed sequences, but is in fact **well-known**. Thus, while Applicants have provided evidence of record that conclusively establishes that those skilled in the art would believe that the specifically claimed sequence encodes an RNA splicing protein, the Examiner has provided absolutely no evidence that directly establishes that the specifically claimed sequence does not encode an RNA splicing protein. Accordingly, the Examiner has not met the burden of overcoming the evidence of record, which compels a finding that the present invention has a patentable utility.

Although Applicants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)), Applicants pointed out in the previous response that as an additional example of the utility of the present nucleotide sequences, the specification details, at least on page 8, lines 22 to 24, that the present nucleotide sequences have utility in assessing gene expression patterns using high-throughput DNA chips. The Examiner states that "it is agreed that the use of polynucleotides in DNA chips (microarrays) is widespread and that the claimed polynucleotides can be attached to DNA chips, for the claimed polynucleotides to be specifically useful in such application, one would require some knowledge or guidance as to the specific biological role of the polypeptides encoded by said polynucleotides, to effectively use the information gathered in tracking the expression pattern of such polynucleotides" (Action at page 7). Applicants respectfully submit that this argument is flawed in a number of respects. First, Applicants have provided a great deal of "knowledge or guidance as to the specific biological role of the polypeptides encoded by said polynucleotides", specifically, as detailed above, that the presently claimed sequences encode proteins involved in RNA splicing. Second, Applicants point out that nucleic acid sequences are commonly used in gene chip applications without any information regarding the function of the encoded protein, or even evidence regarding whether the sequence is actually even expressed. Nucleic acid sequences such as the presently claimed sequences are routinely used by companies throughout the biotechnology

sector **exactly** as they are presented in the Sequence Listing, without **any** further experimentation. Expression profiling does **not** require a knowledge of the function of the particular nucleic acid on the chip - rather the gene chip indicates which DNA fragments are expressed at greater or lesser levels in two or more particular samples. Thus, the present sequence, which has been biologically validated to be expressed, has a much greater utility than sequences that are merely predicted to be expressed based on bioinformatic analysis. This argument therefore completely fails to support the Examiner's allegation that the presently claimed sequences lack a patentable utility.

The Examiner then states that "the asserted use of the claimed polynucleotides in DNA chips is not specific" because "many other polynucleotides including those in the public domain can and are used in DNA chips" (Action at page 8). Applicants respectfully point out that the Examiner is clearly confusing the requirement for a **specific** utility, which is the proper standard for utility under 35 U.S.C. § 101, with that of a **unique** utility, which is clearly an improper standard. As clearly set forth by the Federal Circuit in *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1101 (Fed. Cir. 1991):

> An invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: "[T]he fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding a lack of utility." *Envirotech Corp. v. Al George, Inc.*, 221 USPQ 473, 480 (Fed. Cir. 1984)

Following directly from the quote above, an invention does not need to be the **only way** to accomplish a certain result. Thus, the question of whether or not other nucleic acid sequences can be used to assess gene expression using DNA chips is **completely irrelevant** to the present utility inquiry. The **only** relevant question in regard to meeting the standards of 35 U.S.C. § 101 is whether **every** nucleic acid can be so used - and the clear answer to this question is an emphatic **no**. Applicants point out that only a small percentage (2-4%) of the human genome actually encodes exon data, and these exons are widely interspersed within a given chromosome. Importantly, the holding in the *Carl Zeiss* case is **mandatory legal authority** that essentially controls the outcome of the present case. This case, and particularly the cited quote, **directly** rebuts the Examiner's argument. Furthermore, the requirement for a unique utility is clearly not the standard adopted by the Patent and Trademark Office. If every invention were required to have a unique utility, the Patent and Trademark Office would no longer be issuing patents on batteries, automobile tires, golf balls, golf clubs, and treatments for a variety of human

diseases, such as cancer and bacterial or viral infections, just to name a few particular examples, because examples of each of these have already been described and patented. All batteries have the exact same utility - specifically, to provide power. All automobile tires have the exact same utility - specifically, for use on automobiles. All golf balls and golf clubs have the exact same utility - specifically, use in the game of golf. All cancer treatments have the exact same utility - specifically, to treat cancer. All anti-infectious agents have the exact same broader utility - specifically, to treat infections. However, only the briefest perusal of virtually any issue of the Official Gazette provides numerous examples of patents being granted on each of the above compositions every week. Additionally, if a composition needed to be unique to be patented, the entire class and subclass system would be an effort in futility, as the class and subclass system serves solely to group such common inventions, which would not be required if each invention needed to have a unique utility. Thus, the present sequence clearly meets the requirements of 35 U.S.C. § 101.

Applicants pointed out in the previous response that as the present sequence is a specific marker of the human genome (see below), and such specific markers are targets for the discovery of drugs that are associated with human disease, those of skill in the art would instantly recognize that the present nucleotide sequence would be an ideal, novel candidate for assessing gene expression using such DNA chips. The Examiner states that "(i)n regard to the argument that the claimed polynucleotides can be used as specific markers of the human genome, it is noted that there is no disclosure in the specification as to how is (*sic*) the claimed invention a specific marker of the human genome" (Action at page 8). Applicants respectfully point out that the ability of cDNA molecules, such as the presently claimed sequences, to specifically map the human genome is an inherent feature of any cDNA molecule, and is well-known to those of ordinary skill in the art. As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988). Thus, this argument also fails to support the alleged lack of utility.

Applicants also pointed out in the previous response that as a further example of the utility of the presently claimed polynucleotide, as described in the specification at least at page 3, lines 25-28, the present nucleotide sequences have a specific utility in "identification of coding sequence" and "mapping a unique gene to a particular chromosome". This is evidenced by the fact that SEQ ID NOS:1, 3, 5 and 11 can be used to map 4, 3, 3 and 2 coding exons, respectively, on human chromosome 10 (present within the human chromosome 10 genomic clone disclosed in Genbank

Accession Number AL353719; alignments and the first page from the Genbank report are presented in **Exhibit J**). With regard to the identification of coding sequence, the Examiner states "there is no assurance that the assembled cDNA encoding the polypeptide of SEQ ID NO:2, 4, 6, or 12 is indeed an actual transcript of a gene since it is known in the art that computer-based assembly of genes and their transcripts (cDNA) is not perfect and may lead to wrong splicing of genes" (Action at page 12). The Examiner appears to be under the impression that the presently claimed sequences are merely a "computer-based assembly of genes and their transcripts", which could not be **further** from the truth. Applicants respectfully point out that the specification as originally filed details that the presently claimed sequences "were obtained from a human pituitary gland cDNA library" as well as "RT-PCR products generated using fetal brain, brain, pituitary gland and testis mRNA" (page 7, lines 13-17), and are thus clearly not "computer-based assembly of genes and their transcripts". The presently claimed sequences identify biologically verified exon splice junctions, as opposed to splice junctions that may have been bioinformatically predicted from genomic sequence alone. In fact, Applicants pointed out in the previous response that this is one of the utilities of the presently claimed sequences: "[T]he presently claimed polynucleotide sequence provides biologically validated empirical data (*e.g.*, showing which sequences are transcribed, spliced, and polyadenylated) that *specifically* define that portion of the corresponding genomic locus that actually encodes exon sequence" (the previous response at page 7).

Amazingly, the Examiner next states that "(s)ince applicants provide no experimental evidence to corroborate that the claimed polynucleotides are indeed the actual transcripts of a gene, one cannot reasonably conclude that the claimed polynucleotides provide biologically validated data" (Action at page 12). Applicants respectfully point out one of ordinary skill in the art readily understands that "the actual transcripts of a gene" are mRNA molecules, which are **exactly what was used to obtain the presently claimed sequences**. cDNA libraries are constructed from mRNA, and mRNA was used as the template for the RT-PCR. Applicants are completely at a loss to explain how the Examiner can "reasonably conclude" that the mRNA used by Applicants to obtain the claimed sequences is not "the actual transcripts of a gene". Thus, the Examiner's argument completely and totally fails to support the alleged lack of utility.

With regard to mapping a gene to a unique chromosome, the Examiner states that "such use is not considered specific" because "any human polynucleotide which encodes a protein can be used to detect the particular locus of the corresponding gene" (Action at page 10). Applicants respectfully

point out that the Examiner is once again confusing the requirements of a specific utility with a unique utility. The fact that a small number of other nucleotide sequences could be used to map the protein coding regions in this specific region of chromosome 10 does not mean that the use of Applicants' sequence to map the protein coding regions of chromosome 10 is not a specific utility (*Carl Zeiss Stiftung v. Renishaw PLC, supra*).

Finally, Applicants reiterate that the requirements set forth in the Action for compliance with 35 U.S.C. § 101 do not comply with the requirements set forth by the Patent and Trademark Office ("the PTO") itself for compliance with 35 U.S.C. § 101. While Applicants are well aware of the new Utility Guidelines set forth by the USPTO, Applicants respectfully point out that the current rules and regulations regarding the examination of patent applications is and always has been the patent laws as set forth in 35 U.S.C. and the patent rules as set forth in 37 C.F.R., not the Manual of Patent Examination Procedure or particular guidelines for patent examination set forth by the USPTO. Furthermore, it is the job of the judiciary, not the USPTO, to interpret these laws and rules. Applicants are unaware of any significant recent changes in either 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit that is in keeping with the new Utility Guidelines set forth by the USPTO. This is underscored by numerous patents that have been issued over the years that claim nucleic acid fragments that do not comply with the new Utility Guidelines. As examples of such issued U.S. Patents, the Examiner is invited to review U.S. Patent Nos. 5,817,479, 5,654,173, and 5,552,281 (each of which claims short polynucleotides), and recently issued U.S. Patent No. 6,340,583 (which includes no working examples), none of which contain examples of the "real-world" utilities that the Examiner seems to be requiring. As issued U.S. Patents are presumed to meet all of the requirements for patentability, including 35 U.S.C. §§ 101 and 112, first paragraph (see Section IV, below), Applicants submit that the present polynucleotides must also meet the requirements of 35 U.S.C. § 101. While Applicants understand that each application is examined on its own merits, Applicants are unaware of any changes to 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit, since the issuance of these patents that render the subject matter claimed in these patents, which is similar to the subject matter in question in the present application, as suddenly non-statutory or failing to meet the requirements of 35 U.S.C. § 101. Thus, holding Applicants to a different standard of utility would be arbitrary and capricious, and, like other clear violations of due process, cannot stand.

For each of the foregoing reasons, as well as the reasons set forth in the previous response, Applicants submit that as the presently claimed nucleic acid molecules have been shown to have a substantial, specific, credible and well-established utility, the rejection of claims 1 and 3-16 under 35 U.S.C. § 101 has been overcome, and request that the rejection be withdrawn.

III. Rejection of Claims 1 and 3-16 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claims 1 and 3-16 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse.

Applicants submit that as claims 1 and 3-16 have been shown to have "a specific, substantial, and credible utility", as detailed in section II above, the present rejection of claims 1 and 3-16 under 35 U.S.C. § 112, first paragraph, cannot stand.

Applicants therefore request that the rejection of claims 1 and 3-16 under 35 U.S.C. § 112, first paragraph, be withdrawn.

IV. Rejection of Claims 1 and 3-16 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claims 1 and 3-16 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse.

Applicants detailed the case law surrounding the written description requirement set forth in 35 U.S.C. § 112, first paragraph, in the previous response, and incorporate those comments herein by reference at this point. Even after allegedly considering the relevant case law cited by Applicants, the Examiner still appears to be under the mistaken impression that the presently claimed full length nucleotide sequences lack sufficient written description support because "applicants have not disclosed the function of each and every polypeptide encoded by the claimed polynucleotides" (Action at page 14). Applicants first point out for the record that the function of the claimed sequences has clearly been established, as set forth in Section II, above. However, Applicants once again

respectfully point out that this is **completely irrelevant** to the question of whether the present claims meet the written description requirements under 35 U.S.C. § 112, first paragraph. The case law cited by Applicants in the previous response makes it crystal clear that disclosing "the function of each and every polypeptide encoded by the claimed polynucleotides" is **not the proper legal standard** for meeting the written description requirement under 35 U.S.C. § 112, first paragraph. The Federal Circuit in *Vas-Cath Inc. v. Mahurkar* (19 USPQ2d 1111 (Fed. Cir. 1991); "*Vas-Cath*") held that an "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.*" *Vas-Cath*, at 1117, emphasis in original. By presenting the **actual nucleotide sequence** of SEQ ID NOS:1, 3, 5 and 11 in the Sequence Listing filed with the specification as originally filed, how can the Examiner **possibly** conclude that the inventors were not in possession of the invention?

The Examiner then states that "the written description requirement for a claimed genus may be satisfied through ... disclosure **of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics**" (Action at page 15, emphasis in original). Applicants **completely** agree with this statement by the Examiner, but respectfully point out that the statement **clearly establishes** that the present claims do in fact **meet the written description requirement**. Taking the statement from the Examiner clause by clause, "the written description requirement for a claimed genus may be satisfied through ... disclosure **of relevant, identifying characteristics**". "**[R]elevant, identifying characteristics**" are then defined: (a) **structure or other physical and/or chemical properties**, (b) **by functional characteristics coupled with a known or disclosed correlation between function and structure**, **OR** (c) **by a combination of such identifying characteristics**. In other words, the written description requirement is satisfied by (a), (b) **OR** (c), with the key word being **OR**. The word "or" denotes alternatives. As defined in The American Heritage College Dictionary, Third Edition, the word "or" means "[U]sed to indicate an alternative, usu. only before the last term of a series: *this, that, or the other*". Clause (a) states that the written description requirement may be satisfied by the disclosure of structure. The Federal Circuit has held that an adequate description of a chemical genus "requires a precise definition, such as by structure, formula, chemical name or physical

properties" sufficient to distinguish the genus from other materials. *Fiers v. Sugano*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993; "*Fiers*"). *Fiers* goes on to hold that the "application satisfies the written description requirement since it sets forth the . . . nucleotide sequence" (*Fiers* at 1607). In other words, provision of a structure - the nucleotide sequence - renders the application in compliance with 35 U.S.C. § 112, first paragraph. Thus, in accordance with *Fiers*, by providing the nucleotide sequence of SEQ ID NOS:1, 3, 5 and 11, the present claims are in clearly in compliance with 35 U.S.C. § 112, first paragraph.

More recently, the standard for complying with the written description requirement in claims involving chemical materials has been explicitly set forth by the Federal Circuit:

> In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. *Univ. of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Thus, a claim describing a genus of nucleic acids by structure, formula, chemical name or physical properties sufficient to allow one of ordinary skill in the art to distinguish the genus from other materials meets the written description requirement of 35 U.S.C. § 112, first paragraph. As further elaborated by the Federal Circuit in *Univ. of California v. Eli Lilly and Co.*:

> In claims to genetic material ... a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art cannot, as one can do with a fully described genus, visualize or recognize the identity of members of the genus. (Emphasis added)

Thus, as opposed to the situation set forth in *Univ. of California v. Eli Lilly and Co.* and *Fiers*, the nucleic acid sequences of the present invention are not distinguished on the basis of function, or a method of isolation, but in fact are distinguished by structural features - a chemical formula, *i.e.*, the *sequence itself.*

Using the nucleic acid and amino acid sequences of the present invention (as set forth in the Sequence Listing), the skilled artisan would readily be able to distinguish the claimed nucleic acids from other materials on the basis of the specific structural description provided. Polynucleotides that encode

SEQ ID NO:2, 4, 6 or 12 are within the genus of the instant claims, while those that lack this structural feature lie outside the genus. Claims 1 and 3-16 thus meet the written description requirement.

However, while in no way agreeing with the present rejection, should this rejection be maintained through all levels of appeal available to Applicants, and should this issue be the sole impediment to patentability of the present claims, Applicants hereby state that a deposit of the original clone containing SEQ ID NOS:1, 3, 5 and 11 would be made to the American Type Culture Collection (ATCC), thus removing all question of whether SEQ ID NOS:1, 3, 5 and 11 meet the written description requirement. It is well established through years of court decisions, and recently confirmed by the Federal Circuit in *Enzo Biochem, Inc. v. Gen-Probe, Inc. et al.* (296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002)), a deposit of biological material with the ATCC can be used to satisfy the written description requirement.

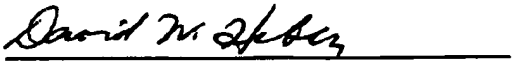
For each of the foregoing reasons, as well as the reasons set forth in the previous response, Applicants submit that the rejection of claims 1 and 3-16 under 35 U.S.C. § 112, first paragraph, has been overcome, and request that the rejection be withdrawn.

V. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Rao have any questions or comments, or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

February 9, 2004
Date



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